NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

CHURCH & DWIGHT CO., INC. : Civ. No. 05-2142 (GEB) (JJH)

Plaintiff, : **MEMORANDUM OPINION**

v.

ABBOTT LABORATORIES,

Defendant.

BROWN, Chief Judge

This matter comes before the Court upon the motion of defendant Abbott Laboratories ("Abbott") for an order permitting it to present its defense of inequitable conduct regarding U.S. Patent Nos. 5,989,921 ("the '921 Patent"), and 6,485,982 ("the '982 Patent") (Docket No. 251). The Court has decided the motion without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reason set forth below the Court denies Abbott's motion.

I. BACKGROUND

This case involves three patents owned by Church & Dwight Co., Inc. ("C&D") related to over the counter pregnancy tests: U.S. Patent Nos. 5,714,389 ("the '389 Patent"), the '921 Patent, and the '982 Patent (collectively, the "Charlton Patents"). A trial was held from January 17, 2008 to February 15, 2008. The jury found that C&D proved by a preponderance of the evidence that Abbott literally infringed, contributed to the literal infringement of, or induced literal infringement of the Charlton Patents as alleged by C&D. Moreover the jury found that

Abbott had not proven by clear and convincing evidence that any of the claims at issue were invalid. The jury also found that C&D showed by a preponderance of the evidence that it was entitled to recover: (1) lost profits in the amount of \$10,250,000.00; and (2) a reasonable royalty of \$4,350,000.00 for infringing sales. Finally, the jury found that C&D proved by clear and convincing evidence that the infringement was willful.

On January 8, 2008, as part of its pretrial brief, C&D made a motion in limine to preclude Abbott's inequitable conduct defense and preclude testimony or evidence concerning the decision of the European Patent Office ("EPO") to revoke the European counterpart to the Charlton patents. On January 15, 2008, Abbott filed papers in opposition to C&D's motion in limine. On January 17, 2008, the Court ruled that Abbott's equitable defenses of inequitable conduct and laches would not be tried to the jury, but instead would be before the Court. See generally General Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405, 1408 (Fed. Cir. 1994) (holding that the Court should ordinarily resolve the fact issues underlying an inequitable conduct defense).

After the jury verdict, the Court requested that Abbott file a brief indicating what it was planning to present to the Court with respect to its inequitable conduct defense. Abbott filed the current motion on March 7, 2008. C&D filed an opposition on March 25, 2008. Abbott filed a reply brief on April 1, 2008.

Three issues are presented by Abbott's present motion: (1) whether, in light of C&D's argument that Abbott did not sufficiently plead inequitable conduct under Rule 9(b), Abbott should be permitted to present evidence that the '921 and '982 patents are unenforceable due to inequitable conduct; (2) whether the EPO revocation decision is material; and (3) whether the

Court should allow the expert testimony proffered by Abbott regarding the alleged inequitable conduct.

The EPO revoked the European counterpart to the Charlton Patents on November 24, 1998, in part, because the claims lacked any inventive step in light of four prior art references. Neither party disputes the fact that these four references were before the United States patent examiner during the prosecution of the '921 and '982 Patents (the "Examiner").

II. DISCUSSION

A. Inequitable Conduct Standard

Patent applicants have a duty to prosecute patents with candor, good faith and honesty.

Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). This duty may be breached by "affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false information, coupled with an intent to deceive." Id. "One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the PTO." Id. An accused infringer "seeking to have a patent declared unenforceable has a heavy burden to meet." Hoffmann-La Roche v. Promega Corp., 323 F.3d 1354, 1359 (Fed. Cir. 2003). Once inequitable conduct has been proved, "the unenforceability of a patent follows automatically." Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1243 (Fed. Cir. 2008).

The first step in performing an inequitable conduct analysis is to determine whether a threshold level of materiality and intent to deceive has been established through clear and convincing evidence. Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1128-29 (Fed.

Cir. 2006). To determine whether a reference is material, courts refer to the materiality standard set forth in PTO Rule 56. Id. Information is deemed material if:

It is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2007).

"Even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive." Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1190 (Fed. Cir. 2006). "[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct." Braun, Inc. v. Dynamics Corp. of Am., 975 F.2d 815, 822 (Fed. Cir. 1992). The Federal Circuit has made clear that intent to deceive cannot be "inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." Purdue, 438 F.3d at 1134 (quoting Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)). To satisfy this requirement, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 439 F.3d 1335 (Fed. Cir. 2006) (quoting Paragon Podiatry Lab. v. KLM Lab., 984 F.2d 1182, 1189

(Fed. Cir. 1993)). "In a case involving the nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference." Molins, 48 F.3d at 1181. While "direct proof of wrongful intent is rarely available, [it] may be inferred from clear and convincing evidence of the surrounding circumstances."

Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998) (quoting LaBounty Mfg. v. United States ITC, 958 F.2d 1066, 1075 (Fed. Cir. 1992)).

"Once threshold findings of materiality and intent are established, the trial court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred." Id. at 1363 (quoting Purdue Pharma, 438 F.3d at 1128). "The tribunal must then carefully balance the materiality and intent: the less material the proffered or withheld information, the greater the degree of intent that must be proven. In contrast, a lesser degree of intent must be proven when the information has a great degree of materiality." N.V. Akzo v. E.I. Du Pont de Nemours & Co., 810 F.2d 1148, 1153 (Fed. Cir.1987).

B. The Parties' Arguments

Abbott contends that the "patents in suit are unenforceable due to inequitable conduct for failure of those involved in prosecuting the C&D patents in suit to disclose the EPO decision revoking the EP counterpart to the C&D patents in suit, which decision was material to the prosecution of the Charlton patents." (Abbott Br. at 3.) Also, Abbott argues that "the USPTO examiner requested C&D's assistance to find the most relevant references among the 200+ references cited by C&D and C&D did not do so." (Id. at 4.) Abbott concludes that "[b]y not bringing this information to the attention of the USPTO, C&D intended to deceive the USPTO into issuing the C&D patents in suit." (Id.) Abbott states that "[t]he key issue in the inequitable

conduct defense relates to . . . the EPO's revocation of the European counterpart to the Charlton patent - and C&D's failure to disclose that document to the U.S. patent examiner." (Abbott Reply Br. at 4.)

C&D opposes the motion and argues that the Court previously ruled that the Foreign EPO Revocation Decision is not material. In any event, C&D argues that the Foreign EPO Revocation Decision is not material. Alternatively, C&D argues that Abbott failed to plead inequitable conduct under Rule 9(b) and that amendment now would be inappropriate. Additionally, C&D argues that it is improper for Abbott's expert to testify on inequitable conduct.

Abbott responds that the EPO Revocation is material and that the Court has not already decided the issue. Abbott also contends that C&D has been on notice of the inequitable conduct defense since October 2006 and thus is not prejudiced by the allege pleading failure.

Additionally, Abbott claims that C&D has waived any argument concerning inadequate pleading. Abbott also argues that if the Court finds Abbott's pleadings deficient, Abbott should be permitted to amend those pleadings. Finally, Abbott contends the testimony by its expert is appropriate under the rules of evidence.

C. The Court's Analysis

1. The Court Previously Determined that the EPO Revocation was Immaterial.

The Court agrees with C&D's contention that the Court previously determined that the EPO Revocation is not material.

Abbott argues that the Court did not determine this, but instead "[d]uring the direct examination of . . . Abbott's . . . expert on invalidity, the Court ruled only that Abbott could not

introduce certain *arguments* made by Carter-Wallace during a European opposition concerning a *different* patent, the May patent owned by another company." (Abbott Br. at 11 (emphasis in original).) Abbott contends that it is "not attempting to introduce and discuss the European revocation decision as evidence relevant to the invalidity of the patents, let alone the revocation decision on a *different* patent." (Id. (emphasis in original).) According to Abbott, it is "offering the revocation decision . . . as a piece of material information that was intentionally withheld from the patent office during prosecution, thereby rendering the asserted claims unenforceable." (Id.)

However, C&D argues that "Abbott could not have legitimately confused the Court's separate rulings on the materiality of the foreign EPO revocation decision and the Court's ruling on the inadmissibility of DTX 530." (C&D Br. at 5.)¹

The Court agrees with C&D. On January 7, 2008, C&D filed, as part of its pretrial brief, a motion in limine seeking to preclude testimony or evidence concerning the foreign EPO Revocation decision. Abbott filed a response to the motion in limine on January 15, 2008. On January 29, 2008, after the motion was fully briefed, the Court expressed its disagreement with Abbott's argument and ruled that "the underlying information might be material to the patent examiner, but the ruling itself would not [be.]" (Jan. 29, 2008 (sidebar) Tr. at 12:14-17.) Thus the Court granted the motion of Church and Dwight.²

¹ DTX 530 is a notice of opposition relating to the May patent, not a foreign EPO revocation decision relating to the Charlton Patent.

² Abbott's argument in its reply brief that the Court's statement on February 15, 2008 that the Court "will deal with that when it's raised" indicates that the Court did not decide this issue is mistaken. (Abbott Reply Br. at 1-2; Feb. 15, 2008 (sidebar) Tr. at 18:20-19:3.) The Court was merely stating that it would deal with the parties' disagreements regarding inequitable conduct

During the same sidebar, counsel for Abbott stated that there was "a different issue" for the Court to address. (Id. at 12:19-21.) Counsel stated that Abbott was "not interested in putting in the decision itself" but "the underlying information" regarding the May patent. (Id.) The Court noted that this was "a different issue from what you briefed." (Id. at 13:2-11.) The Court stated that "[t]he underyling art is relevant. The arguments addressed to foreign law are clearly not." (Id. at 13:19-20.) However, the Court did not resolve this second issue because Counsel for Abbott stated that "the best thing is for [the parties] to talk about it" and that if the parties "have a problem we'll raise it tomorrow morning." (Id. 14:24-15:11.)

Abbott now concentrates on this "different issue" and apparently ignores the Court's ruling on C&D's motion in limine seeking to preclude testimony or evidence concerning the foreign EPO Revocation decision. Although Abbott correctly states that the Court addressed "certain arguments made by Carter-Wallace during a European opposition concerning a different patent," (Abbott Br. at 11), the Court also addressed "the foreign EPO decision" that "was raised by counsel for Church and Dwight in their trial brief filed on January the 8th." (Jan. 29, 2008 Sidebar Tr. at 11-12.) The Court specifically recounted C&D assertion "that the foreign EPO revocation decision is not material" under <u>ADT v. Liddell</u>, 159 F.3d 534 (Fed. Cir. 1998). (<u>Id.</u> at 12.) Following <u>ADT</u>, this Court ruled that "the underlying information might be material to the patent examiner, but the ruling itself would not, therefore, the motion of Church and Dwight is

after the jury verdict. Similarly, Abbott contends in its reply brief that the Court's statement prior to the parties' opening statements that "[t]he defenses are for me, and you can try them" constituted a ruling on C&D's motion in limine regarding the inequitable conduct defense. (Abbott Reply Br. at 4.) Abbott is wrong. The Court merely informed the parties that any trial on the equitable defenses would be before the Court, not the jury; the Court did not, at that time, rule on C&D's motion in limine.

granted." As discussed in more detail below, Abbott has not provided the Court with any reason to revisit its grant of C&D's motion in limine.

2. The Court Properly Determined That The Revocation Decision By The EPO Is Not Material.

Abbott relies on five arguments in contending that the EPO revocation decision is material. First, Abbott argues that the EPO decision is material because the Examiner stated that "applicants are respectfully requested to comment on the materiality of each of the cited documents which derived from multiple European proceedings." (PTX6 at 110.) Second, Abbott argues that the District of Massachusetts in Inverness Med. Switzerland GmbH v. Acon Labs., Inc., 323 F. Supp. 2d 227 (D. Mass. 2004) already opined that this EPO revocation decision is likely material to the Charlton Patents. (Abbott Br. at 8.) Third, Abbott claims that C&D mistakenly relies on comments made by Abbott's counsel in a case in which Abbott's counsel represented Barr Laboratories. Fourth, Abbott contends that the ATD case from the Federal Circuit is not controlling because the document that was not disclosed in ATD, an administrative patent search report from a foreign patent office, "is a far cry from the decision of the European patent office to revoke an issued patent." (Id. at 9 (emphasis omitted).) Finally, Abbott argues that the Court should not find "the references and the revocation immaterial, especially in view of the recent and contrary position of the PTO." (Id. at 11.)

The Court does not find Abbott's arguments to be persuasive. First and most importantly, the Court finds that <u>ATD</u> controls here. Abbott has cited no authority to support the distinction it draws between international search reports and foreign revocation decisions. Moreover, Abbott does little to explain why this distinction should make a difference, except to state that an

international search report is a "type of administrative document [that] is a far cry from [the revocation] decision." (Abbott Br. at 9 (emphasis omitted).) The <u>ATD</u> court stated that "[a]lthough international search reports may contain information material to patentability if they contain closer prior art than that which was before the United States examiner, it is the reference itself, not the information generated in prosecuting foreign counterparts, that is material to prosecution in the United States." 159 F.3d at 547. The <u>ATD</u> court concluded that "[t]he details of foreign prosecution are not an additional category of material information." <u>Id.</u> This Court concludes that the same reasoning should apply to the EPO revocation decision. <u>See Softview Computer Products Corp. v. Haworth, Inc.</u>, No. 97 Civ. 8815, 2000 WL 351411, at *7 (S.D.N.Y. March 31, 2000) ("Haworth's alleged failure to inform the PTO of the EPO's evaluation of the Sieman's patent cannot constitute fraud, because it does not meet the materiality requirement for a showing of fraud."). The prior art referenced in the EPO revocation decision may be material, but the "information generated," by the EPO, namely the revocation decision itself, is not "material to prosecution in the United States." <u>Id.</u>

The Court is also not persuaded by Abbott's reference to Inverness Med. Switzerland

GmbH v. Acon Labs., Inc., 323 F. Supp. 2d 227 (D. Mass. 2004), wherein the District of

Massachusetts concluded, on a motion for preliminary injunction, that it was *likely* that the

defendant could show that the EPO revocation decision was material. Of course, Inverness, a

District of Massachusetts decision, is not binding on this Court. Moreover, this Court does not

find the Inverness case persuasive here, because the *likelihood* of showing materiality is not at

issue. As discussed above, this Court actually ruled on the materiality of the EPO revocation and
found that the decision itself was not material. Moreover, although the Inverness court

acknowledged that the "[d]etails of foreign prosecutions, as opposed to the prior art references cited therein, do not generally constitute an independent category of material information," the court seemingly made an exception "in light of the fact that the examiner had previously requested assistance in dealing with the extremely large number of prior art references." 323 F. Supp. at 249. The Court sees no reason to make such an exception. The Examiner's request for "comment on the materiality" of documents, "which derived from multiple European proceedings" is besides the point because the Examiner did not ask for the EPO's analysis or the results of any EPO proceeding. (PTX 4 at 469; PTX 6 at 903, 927.)

Additionally, as Abbott admits, "the recent and [allegedly] contrary position of the PTO" referenced in Abbott's brief, was a determination by the PTO that the "references relied on in the EPO revocation were material to patentability and therefore were not cumulative." (Abbott Br. at 10-11.) This position is consistent with the Court's ruling.

Finally, Abbott's argument that C&D mistakenly relies on comments made by Abbott's counsel in another case is irrelevant because the Court did not rely on the comments in determining the law. Thus, the Court properly determined that the revocation decision by the EPO is not material.

3. Remaining Inequitable Conduct Issues

C&D argues that Abbott has no remaining inequitable conduct defense because the first requisite for inequitable conduct - materiality - does not exist. Abbott has not identified any other material omission. Although, Abbott states that in addition to the failure to provide the EPO revocation decision to the USPTO, "the USPTO examiner requested that the patent applicant assist in narrowing down the 200+ references cited by the applicant, the applicant did

not identify the four references that were the subject of the EPO opposition," the Court concludes that this is not a material omission. Instead, the references that were the subject of the EPO opposition is an immaterial "detail[] of [a] foreign prosecution." Thus, there is no remaining inequitable conduct defense.³

D. CONCLUSION

For the foregoing reasons, Abbott's motion (Docket No. 251) is denied.

Dated: June 23, 2008

s/ Garrett E. Brown, Jr. GARRETT E. BROWN, JR., U.S.D.J.

³In light of this ruling, the Court need not address whether the defense was adequately pled or whether to allow the testimony of Mr. Mossinghoff.